Dated: -23.12.2022

# CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health and Family Welfare (Government of India)
2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg,
Opposite Police Station Chankaya Puri, New Delhi-110021

Telephones: 011-21410905, 21410906
Email: gmproc.cmss@gmail.com
agminderjeetyadav.cmss@gmail.com

**Tender No: CMSS/PROC/2022-23/NTEP/023**
For
Procurement of Tablet Isoniazid 100mg Dispersible, Tablet Isoniazid 100mg &
Tablet Isoniazid 300mg

**Minutes of Pre-bid meeting held on 05th December 2022 at 12.00 Noon**

1. Following officials were present during the Pre-bid meeting:-

   (i) Ms. Anjana, GM (Procurement), CMSS
   (ii) Mr. D.Mohapatra, GM (Finance), CMSS
   (iii) Dr. Alok Mathur, Addl. DDG, CTD MoHFW
   (iv) Ms. Akansha Jain, AGM (QA), CMSS
   (v) Mr. Inderjeet Yadav, AGM (Proc), CMSS

2. Following representative from prospective bidder was present during the Pre-bid meeting:-

   (i) Mr. Mukul Jerath, Lupin Ltd.
   (ii) Mr. Kuldeep waklilor, Lupin Ltd.

**Minutes of Pre-bid meeting**

| S. No. | Query Received from Prospective Bidders | Standard Tender Clause | Response |
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| **A** | **M/s Macleods** | | |
| 1. | **Query:**<br>As per this clause, we understand COPP as per any | **Eligibility Criteria:**<br>**Clause 4(b).** | Clarified as; Certificate of Pharmaceutical Product (COPP) as per tender may |

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| | Pharmacopeia as well as for any country (India or any exporting country) will be acceptable. Please confirm. | **(b):** Tenderer shall be a manufacturer of the quoted product and have a valid own manufacturing license in the indicated pharmacopeia (in the technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP. The manufacturing license & COPP should be valid on the date of tender opening packet 1. | be accepted irrespective of Country.<br>COPP should be valid on the date of tender opening packet 1. |
| **2.** | **Query:**<br><br>a) Please confirm two years of manufacturing experience as per any pharmacopeia i.e, IP, BP, USP, or IH will be acceptable under this clause.<br><br>b) And also, marketing experience either within India or any exporting country shall be acceptable.<br><br>c) Please clarify what you mean by regulated products. | **Eligibility Criteria:**<br>**Clause 4(c) & 6.1(e)**<br><br>**(c):** For all regulated products, the bidder should have at least two years of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) less than two years ago. DCG(I) is permission shall be required for all newly regulated products to this effect.<br><br>**Clause 6.1(e)**<br>Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e 2020-21 & 2021-22 for compliance of tender clause 4.c. | Amended As;<br>For Sch. I- Market standing certificate & Long term stability data may be provided in any previously approved pharmacopeia i.e IP/BP/USP/INH etc.<br><br>For Sch. II & III- No change, Market standing certificate and Long term stability data is to be provided in IP only. |

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| 3. | **Query:**<br>This clause may please be amended and the condition of a decrease of quantities should be removed as we need to book raw materials against payment of advances because of high fluctuations in the raw material market and a decrease of quantities affects our costing. | **Other Conditions:**<br>**Clause 10.1**<br><br>(I) The details of the annual required quantity of items are shown in Annexure-I<br>(i) Central Medical Services Society (CMSS) will have the right to increase or decrease up to 25% of the number of goods and/or services specified in the schedule of requirements without any change in the unit price or other terms and conditions at any time of award of Contract. | No Change |
| 4. | **Query:**<br><br>Please confirm, if the tendered product is in any pharmacopeia other than IP then a manufacturing license in any pharmacopeia other than IP will be considered and the BID will not be rejected. | **Technical Specification,**<br>**Clause 6(c)**<br><br>The Tenderer should furnish the Manufacturing License valid on tender opening for each item quoted been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only. | Amended as:-<br>For Sch. I- If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only. For drugs which are not available in IP, other official Pharmacopeia (s) are applicable. If a drug is not available in any of the official pharmacopeia, 'In House' standards are applicable as per Drugs and Cosmetics Act 1940 and Rules there under.<br><br>**Bidder is requested to submit an undertaking that the drug is not available in IP or any other approved pharmacopeia.**<br><br>For Sch. II & III- Manufacturing License is to be submitted in IP Only.<br><br>The manufacturing License |

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| | | | should be valid on the date of tender opening packet 1. |
| 5. | **Query:**<br><br>Please clarify what is meant by conditional bids. | **Technical Specification, Clause 6.2(b)**<br>Conditional Bids shall be summarily rejected. | Clarified as; Conditional bids means there is any deviation from the tender terms & conditions. |
| 6. | **Query:**<br><br>This clause may please amended and the conditio placing 50% addit quantities may please be removed because our costin is based on the indicativ quantities in the tender to b kept effective till the validit of the bid. | **Other Conditions:**<br>**Clause 10.1(ii)**<br><br>In the exceptional situation where the requirement is of an emergent nature and it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place a repeat order up to 50% of the quantity of the goods and/or services contained in the running tender/contract up to a period of twelvemonths from the earliest date of acceptance of award at the same rate or a rate negotiated (downwardly) with the existing vendors considering the reasonability of rates based on prevailing market conditions and the impact of the reduction in duties and taxes etc. | No Change |

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| 7. | **Query:**<br><br>Please clarify how 25% of batch supply cost will be determined. | **Quality Control**<br>**Clause 16.8(c)**<br>In the event of the samples of Drugs/goods supplied fail in quality tests or are found to be not as per specifications at any of the testing stages (as mentioned in clause no. 16.3),depending upon the type, nature, and seriousness of the failure, consequences resulting from such default, availability of alternate sources, the CMSS is at liberty to either :<br>(i)Ask the supplier to replace the entire quantity of relevant batches, in addition to the imposition of penalty @ 25% of batch supply cost | Clarified as;<br>If the batch fails in QC report, then the batch shall be replaced by the supplier. In addition to this, 25% penalty would be levied on the total cost of the failed batch. It will be determined on the total cost of the failed batch. |
| 8. | **Query:**<br><br>Please consider part payment after the supply of10% of the item order in the individual tranche/lot in the purchase order provided a report of standard quality of samples testing is received from approval laboratories of CMSS as the quantities to be supplied under schedule 1 are very large and release of payment on completion of 50% of the supplies in the individual tranches/lot largely affect our working capital requirements, hence would request you to consider the release of payment on starting completion of 10% supplies. | **Payment Provision,**<br>**Clause 17.5**<br><br>Lot/Tranche/PO vise Part payments for supply will be considered only after completion of supply of at least 50%quantity ordered in the individual Purchase Order/Lot/Tranche PROVIDED original consignee receipts (or on GeM by consignee for the receipt, with original CRC to be submitted before next payment is released) are produced and the quality pass reports of Standard Quality on samples testing are received from approved laboratories of CMSS. | No Change |

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| 9. | **Query:**<br><br>Liquidated damages of 2.5% per week are very high. Please consider 0.25% or less per week to a maximum of 10%. | **Liquated Damages and Other Penalty,**<br>**Clause18.2**<br>If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty. | No Change |
| 10 | **Query:**<br><br>**a**) Please confirm product with a Shelf life of 24 months is acceptable.<br><br>b) We have long-term stability data as per USP. We would like to bring to your kind attention that the quality and performance parameters in IP/BP/USP are all same and the specifications available in the stability data assigned by OXALIS LABS are all well covered and very well in limit<br>**also.** Hence request you to please consider. | **Specific Requirement,**<br><br>**Regarding specific requirements:**<br>E. Shelf Life:<br><br>**Sch. I – Isoniazid 100mg Dispersible** Shelf life should be minimum 36 months from the date of manufacture.<br><br>**Sch. II - Isoniazid 100mg -** Shelf life should be minimum 36 months from the date of manufacture.<br><br>**Sch. III - Isoniazid 300mg -** Shelf life should be minimum 36 months from the date of manufacture. | As this is a part of Technical Specifications, the required shelf life of the drugs mentioned in Sch I, II, & III cannot be changed. |

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| | | **Clause 6.1(m)**<br>Long Term (Real Time) Stability Data of the quoted product in<br>specified packing for at least for 3 batches, to support shelf life. | |
| **11.** | **Query:**<br><br>Apart from the Manufacturing license what else is required from the bidder to submit under this clause? | **Specific Requirement,**<br><br>**Regarding Specific requirements:**<br>The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India. | Clarified as; Manufacturing license for domestic use only is acceptable. |
| **12.** | **Query:**<br><br>If the tendered drug is in BP or USP or In-house pharmacopeia, will the manufacturing license in BP or USP or other pharmacopeias apart from IP is acceptable? Please advise. | **Specific Requirement,**<br>**Regarding Specific requirements:**<br>If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only. For drugs which are not available in IP, other official Pharmacopeia (s) are applicable. If a drug is not available in any of the official pharmacopeia, 'In House' standards are applicable as per Drugs and Cosmetics Act 1940 and Rules there under. | For drugs that are not available in IP, other official Pharmacopeia (s) are applicable. If a drug is not available in any of the official pharmacopeias, 'In House' standards are applicable as per the Drugs and Cosmetics Act 1940 and the Rules there.<br><br>**Bidder is requested to submit an undertaking that the drug is not available in IP or any other approved pharmacopeia.** |

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| **B** | **M/s J. DUNCAN** | | |
| **1.** | **Query:**<br><br>**Tender Clause 6.2(d) Amended as :**<br>Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/- or more) | **Technical Specification, Clause 6.1(d)**<br><br>Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/-) | **Tender Clause 6.2(d) Amended as :**<br>Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/- or more) |
| **2.** | **Query:**<br><br>**Tender Clause 6.2(e)**<br>Amended as:<br>For Sch. I- Tablet Isoniazid 100mg Dispersible<br>Manufacturing and Market Standing Certificate Market Standing Certificate issued by the Licensing Authority as a manufacturer for item (Tablet Isoniazid) for the last 2 years i.e 2020-21 & 2021-22.<br>OR<br>Manufacturing and Market Standing Certificate Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 1 year i.e 2021-22.<br>**Reasons:-** As on date Products (Tablet Isoniazid 100mg Dispersible) are not included in Indian Pharmacopoeia or Any other Pharmacopeia. We are reputed manufacturer of Isoniazid 100mg & 300mg. we are past supplier of CMSS above mentioned drugs.<br><br>**For Sch. II & III –**<br>**no change suggested.** | **Technical Specification, Clause 6.1(e)**<br><br>Manufacturing and Market Standing Certificate Market Standing Certificate / issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e 2020-21 & 2021-22 for compliance of tender clause 4.c. | Amended As;<br>For Sch. I- Market standing certificate & Long term stability data may be provided in any previously approved pharmacopeia i.e IP/BP/USP/INH etc.<br><br>For Sch. II & III- No change, Market standing certificate and Long term stability data is to be provided in IP only. |
| **3.** | **Query:**<br>**Tender Clause no 6.2 (m) :-** | **Technical Specification, Clause no 6.1 (m)** | Amended As;<br>For Sch. I- Market standing |

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| | **Amended as:-**<br>For Sch. I- Only Accelerated data required. in specified packing for at least for 3 batches.<br>**Reasons:-** As on date Products (Tablet Isoniazid 100mg Dispersible) are not included in Indian Pharmacopoeia or Any other Pharmacopeia. We are reputed manufacturer of Isoniazid 100mg & 300mg. we are past supplier of CMSS above mentioned drugs.<br>**For Sch. II & III - no change suggested.** | Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life. | certificate & Long term stability data may be provided in any previously approved pharmacopeia i.e IP/BP/USP/INH etc.<br><br>For Sch. II & III- No change, Market standing certificate and Long term stability data is to be provided in IP only. |
| **4.** | **Query:**<br>For Sch. I- relaxed COPP conditions.<br>OR Allow the same strength film coated tablet/ Dispersible tablet.<br>Please refer technical specification- As per requirement of technical specification only WHO GMP standard.<br>**Reasons:-** As on date Products (Tablet Isoniazid 100mg Dispersible) are not included in Indian Pharmacopoeia or Any other Pharmacopeia. We are reputed manufacturer of Isoniazid 100mg & 300mg. we are past supplier of CMSS above mentioned drugs.<br>For Sch. II & III - no change suggested. | **Technical Specification, Clause 6.1(f )**<br><br>A valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP and a valid WHO-GMP | Clarified as; Certificate of Pharmaceutical Product (COPP) as per tender may be accepted irrespective of Country.<br>COPP should be valid on the date of tender opening packet 1. |
| **5.** | **Query:**<br>**Tender Clause 18.2 amended as:**<br><br>If the supply reaches the designated consignee places or CMSS Warehouse after | **Liquidated Damages and Other Penalty, Clause 18.2**<br><br>If the supply reaches the designated consignee places or CMSS Warehouse after | No Change |

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| | scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 0.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty. | scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied *(a)* @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty. | |
| 6. | **Query:**<br>**Delivery Schedule for Sch. I & II amended as:**<br>1st tranche: 50% of the total quantity- to be received within 120 days from issue of LOA<br>2nd tranche: 25% of the total quantity to be received within 121-240 days from issue of LOA<br>3rd tranche: 25% of the total quantity to be received within 241-360 days from issue of LOA | **Delivery Schedule,**<br><br>**Delivery Schedule for Sch. I & II:**<br>**1st tranche:** 50% of the total quantity- to be received within 60 days from issue of LOA<br>**2nd tranche:** 25% of the total quantity to be received within 180-210 days from issue of LOA<br>**3rd tranche:** 25% of the total quantity to be received within 270-300 days from issue of LOA | **Delivery Schedule for Sch. I & II amened as:**<br>**1st tranche:** 50% of the total quantity- to be received within 90 days from issue of LOA<br>**2nd tranche:** 25% of the total quantity to be received within 180-210 days from issue of LOA<br>**3rd tranche:** 25% of the total quantity to be received within 270-300 days from issue of LOA |

**Rest all Terms and Conditions remains same.**

General Manager (Procurement)

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